DEC 1 5 2003

November 26, 2003

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## SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, Linvatec Corporation is hereby submitting the Special 510(k) Summary of Safety and Effectiveness for the Trident Resection Ablator 510(k) Number _____.

### A. Submitter

Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908
Registration Number: 1017294

### B. Company Contact

Laura D. Krejci, RAC
Manager, Regulatory Affairs
(727) 399-5234 Telephone
(727) 399-5264 FAX

### C. Device Name

Trade Name: Trident™ Resection Ablator

Common Name: Shaver Blade, Electrosurgical Electrode

Classification Names: Arthroscope, 21 CFR 888.1100,
Electrosurgical cutting and coagulation device and accessories, 21 CFR 878.4400

Proposed Class/Device: Class II

Product Code: HRX, GEI

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Summary of Safety and Effectiveness
Trident Resection Ablator
510(k) # _____
November 26, 2003

## D. Predicate/Legally Marketed Devices

| | |
|---|---|
| Resection Ablator<br>Linvatec Corporation | 510(k) # K013369 |
| UltrAblator ®<br>Linvatec Corporation | 510(k) # K030720 |

## E. Device Description

The Trident Resection Ablator is a combination of a 4.2mm Linvatec arthroscopic shaver blade and a Linvatec UltrAblator® monopolar electrode. The product configuration combines the mechanical resection of a shaver blade and the ablation and hemostasis functions of an electrode. The Trident Resection Ablator is supplied sterile, single use.

The modification to the Trident Resection Ablator described in this Special 510(k) is a change in the material formulation of the electrical insulation coating. This modification does not affect the device's intended use, fundamental scientific technology, performance specifications or labeling.

## F. Intended Use

The Trident Resection Ablator is intended to be used in arthroscopic procedures for resection and ablation of soft tissue, and hemostasis of blood vessels.

## G. Substantial Equivalence

The Trident Resection Ablator is substantially equivalent in design, technology and intended use to the existing Resection Ablator and UltrAblator Electrode. Testing has been conducted to assure that the change in the material formulation of the insulation coating does not raise any new issues regarding safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2003

Ms. Laura D. Krejci, RAC
Manager, Regulatory Affairs
Linvatec Corporation
11311 Concept Boulevard
Largo, Florida 33773-4908

Re: K033748
Trade/Device Name: Trident™ Resection Ablator
Regulation Number: 21 CFR 878.4400; 21 CFR 888.1100
Regulation Name: Electrosurgical cutting and coagulation device and accessories; Arthroscope
Regulatory Class: II
Product Code: GEI, HRX
Dated: November 26, 2003
Received: December 1, 2003

Dear Ms. Krejci:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K033748

Device Name: Trident™ Resection Ablator

Indications For Use:

The Trident Resection Ablator is intended to be used in arthroscopic procedures for resection and ablation of soft tissue, and hemostasis of blood vessels.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K033748